3.0 510(k) Summary

Sponsor:
Synthes
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6604

Contact:
Amnon Talmor
Synthes
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6604

Device Name: Synthes Epoca Shoulder Prosthesis System, HA Coated Stems

Classification: Class II, §888.3670 – Shoulder joint metal/polymer metal nonconstrained or semi-constrained porous-coated uncemented prosthesis

Class II, §888.3690 – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis

Predicate Devices: Synthes Epoca Shoulder Prosthesis System

Howmedica Osteonics Solar PureFix HA Shoulder

Device Description: The Synthes Epoca Shoulder Prosthesis System is intended for partial or total replacement of the shoulder joint. The Synthes Epoca Shoulder Prosthesis System consists of metallic cemented and uncemented fixation stems (available with HA coating), humeral heads, an eccenter offset adjustment mechanism, and UHMWPE glenoid components. The components are available in a variety of sizes for primary and revision applications. The components are manufactured from CoCrMo Alloy, Titanium, and Ultra-High Molecular Weight Polyethylene (UHMWPE).

Intended Use: The Synthes Epoca Shoulder Prosthesis System is intended for use as a hemi or total shoulder replacement. It is a single use device for reconstruction of the glenohumeral joint in the presence of complex fractures (i.e., 3 and 4 part), revision of failed fixation or arthroplasty, post-traumatic mal-union and disabled, painful shoulder joints resulting from various forms of arthropathy such as osteoarthritis, rheumatoid arthritis, traumatic arthritis or avascular necrosis and other pathologies where arthrodesis is not acceptable. The Press-fit Titanium Plasma Sprayed Humeral Stems are for cementless use only.

Substantial Equivalence: The information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2009

Synthes (USA)
% Mr. Amnon Talmor
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K083439
Trade/Device Name: Synthes Epoca Shoulder Prosthesis System
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: II
Product Code: MBF, HSD, KWT
Dated: November 19, 2008
Received: November 24, 2008

Dear Mr. Talmor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use

510(k) Number (if known): K083439

Device Name: Synthes Epoca Shoulder Prosthesis System

Indications for Use: The Synthes Epoca Shoulder Prosthesis System is intended for use as a hemi or total shoulder replacement. It is a single use device for reconstruction of the glenohumeral joint in the presence of complex fractures (i.e., 3 and 4 part), revision of failed fixation or arthroplasty, post-traumatic mal-union and disabled, painful shoulder joints resulting from various forms of arthropathy such as osteoarthritis, rheumatoid arthritis, traumatic arthritis or avascular necrosis and other pathologies where arthrodesis is not acceptable. The Press-fit Titanium Plasma Sprayed Humeral Stems are for cementless use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083439